

R E M A R K S

In reply to Item No. 4 at the top of page 3 of the January 16, 2004 Office Action, submitted concomitantly herewith is a REQUEST FOR FULLY INITIALED COPY OF SHEET 1 OF FORM PTO/SB/08B DATED OCTOBER 25, 2001, including legible copies of the Matsuoka et al. and the Shiao et al. publications.

The amendment to claims 40 and 56 of a "ML-236B producing micro-organism which belongs to the *Penicillium* genus" is supported in the specification on page 9, line 10 to page 10, line 1.

New claims 61 and 65 are also supported on page 9, line 10 to page 10, line 1 of the specification.

New claims 62 and 63 are supported by the first sentence on page 6 of the specification.

With respect of Rule 116, entry of the AMENDMENT is respectfully requested, since the AMENDMENT serves to address issues raised in the Final Rejection and places the application in a better position for an appeal, should an appeal be needed.

The Abstract that was enclosed with the AMENDMENT UNDER 37 CFR 1.111 dated October 8, 2003 was objected to for the reasons set forth in Item No. 6 on page 3 of the Office Action.

The undersigned had a telephone interview with the Examiner on January 22, 2004, wherein the Examiner stated that the wrong Abstract of the Disclosure was scanned into the file of the above-identified application. The Examiner said that she was able to locate the correct Abstract of the Disclosure for the above-identified application and that she found no objections to the Abstract of the Disclosure for the present application.

In view of the above, withdrawal of the objection is respectfully requested.

Claims 40 to 43 and 56 to 60 were rejected under 35 USC 112, first paragraph for the reasons indicated in Item No. 16 on pages 5 to 6 of the Office Action and Item No. 20 bridging pages 8 and 9 of the Office Action, wherein the position was taken that the specification was enabled for methods using only host cells that contain the biosynthetic pathway for ML-236 (for example, *P. citrinum*), but does not reasonably provide enablement for methods using host cells that do not contain the biosynthetic pathway for ML-236B.

On page 6, lines 7 to 8 of the Office Action, the following was stated: "the only working examples with *mlcR* involve its transformation into *P. citrinum*."

The applicants respectfully submit that the originally filed specification enables one of ordinary skill in the art to use any ML-236B producing *Penicillium* strain as a host cell in the method of claim 40. This position is supported by the DECLARATION UNDER 37 CFR 1.132 of Yuke ABE dated October 6, 2003. A copy of the October 6, 2003 ABE DECLARATION is of record. Submitted concomitantly herewith is the originally executed October 6, 2003 ABE DECLARATION.

The October 6, 2003 ABE DECLARATION clearly shows that the gene corresponding to *mlcR* has been conserved between several *Penicillium* strains (including a *Eupenicillium* strain) which can produce ML-236B. All the ML-236B producing strains tested in the October 6, 2003 ABE DECLARATION have a gene (or genes) corresponding to *mlcR*.

With respect to the October 6, 2003 ABE DECLARATION, it is noted that "*Eupenicillium sinaicum*" (which is a microorganism that was tested in the October 6, 2003 ABE DECLARATION) is an anamorph of *Penicillium sinaicum*. In this regard, please see the enclosed copy of an article by S. Udagawa and S. Ueda ("A New *Eupenicillium* Species With Reticulately Ornamented Ascospores", Mycotaxon, XIV, pp. 266-272 (1982)).

The Examiner is apparently trying to limit applicants only to their working examples and this is improper. See In re Anderson, 176 USPQ 331, 333 (CCPA, 1973), where the Court held as follows:

"we do not regard §112, first paragraph, as requiring a specific example of everything within the scope of a broad claim...What the Patent Office is here apparently attempting is to limit all claims to the specific examples, notwithstanding the disclosure of a broader invention. This it may not do."

Further support for such proposition is found in In re Kamal and Rogier, 158 USPQ 320, 323 (CCPA, 1968). Quoting from In re Grimme, Keil, and Schmitz, 124 USPQ 499, 502 (CCPA, 1960), the Court stated as follows:

"It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it, or even to name every such species. It is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it."

Indeed, examples per se are not required to satisfy the requirements of 35 U.S.C. 112, first paragraph. See In re Strahilevitz, 212 USPQ 561, 562-563 (CCPA, 1982); In re Stephens, 188 USPQ 659, 660-662 (CCPA, 1976); In re Borokowski, 164 USPQ

642, 645-646 (CCPA, 1970); In re Gay, 135 USPQ 311, 316 (CCPA, 1962).

The Court held in In re Robins, 166 USPQ 552, 555-556 (CCPA, 1970) that working examples are only one means of satisfying the enablement requirement of 35 U.S.C. 112, and that the mere listing of specific compounds, chemicals, solvents, cross-linking agents, etc., in the specification would in most cases provide suitable evidence of enablement equivalent to specific working examples utilizing each of the various components. In this regard, please see the listing of *Penicillium* species on page 9, line 10 to page 10, line 1 of the specification.

The disclosure as set forth by the applicants in the application must be given the presumption of correctness and operativeness by the Patent and Trademark Office. The only relevant concern of the Patent and Trademark Office is the truth of the assertions in the application. In any event, the burden is on the Patent and Trademark Office whenever a rejection is made for lack of enablement under Section 112. The Examiner must explain why she doubts the truth or accuracy of the statements in a supporting disclosure to which she objects. She must back up

such assertions with acceptable evidence or reasoning which contradicts applicants' contentions. See, for example, In re Marzocchi, 169 USPQ 367, 369-370 (CCPA, 1967) and In re Bowen, 181 USPQ 48, 50-52 (CCPA, 1974).

It is respectfully submitted that the Examiner in the case at hand has not carried her burden of showing the applicants' specification to be untrue or inaccurate.

It should be further noted that only those skilled in the art must be enabled, not the general public. In re Storrs, 114 USPQ 293, 296-297 (CCPA, 1957).

Claims 56 to 58 were rejected under 35 USC 112, first paragraph for the reasons set forth in Item No. 19 on page 8 of the Office Action.

As requested in the Office Action, the paragraph bridging pages 31 and 32 of the specification was amended to indicate the address of the depository to avoid this rejection.

It is therefore respectfully submitted that the present claims and specification comply with all the requirements of 35 USC 112.

Claims 40, 45 and 60 were rejected under 35 USC 102 as being anticipated by WO 01/12814 for the reasons set forth in Item No.

18 on page 7 of the Office Action and Item No. 21 at the bottom of page 9 of the Office Action.

At the middle of page 7 of the Office Action, it was stated that the Examiner agreed with applicants' position that one of ordinary skill in the art would not have determined the cDNA sequence from the genomic sequence taught by WO 01/12814 and thus claim 41 was not included in the instant rejection.

It is respectfully submitted that claim 40, which now recites that the vector does not comprise at least one polynucleotide selected from the group consisting of a polynucleotide encoding mclA corresponding to SEQ ID NO 44, a polynucleotide encoding mlcB corresponding to SEQ ID NO 46, a polynucleotide encoding mlcC corresponding to SEQ ID NO 48, a polynucleotide encoding mlcD corresponding to SEQ ID NO 50 and a polynucleotide encoding mlcE corresponding to SEQ ID NO 38, patentably distinguishes over WO 01/12814, because WO 01/12814 discloses only polynucleotides which encode all of mlcA to mlcE and mlcR.

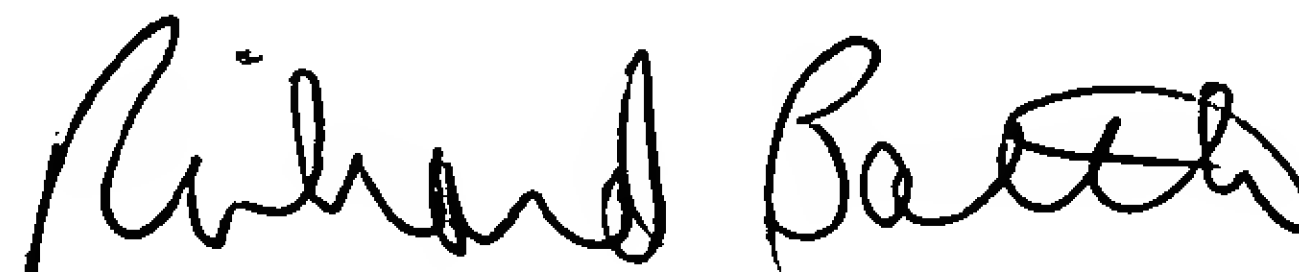
In view of the above, withdrawal of the 35 USC 102 rejection is respectfully requested.

Reconsideration is requested. Allowance is solicited.

Enclosed is a check for \$108 in payment of six additional independent claims.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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- Encs.: (1) REQUEST FOR FULLY INITIALED COPY OF SHEET 1
OF FORM PTO/SB/08B DATED OCTOBER 25, 2001
- (2) copy of S. Udagawa and S. Ueda, "A New
Eupenicillium Species with Reticulately Ornamented
Ascospores", Mycotaxon, Vol. XIV, No. 1, 266-272
(1982)
- (3) Originally executed DECLARATION UNDER 37 CFR 1.132
of Yuki ABE dated October 6, 2003
- (4) Check for \$108